

REMARKS

Prior to the Office Communication mailed February 5, 2008, claims 28, 31, 34-44, 49 and 53 were pending with claims 50-51, 55-56 and 58 having been previously withdrawn. The Office Communication indicates that all pending claims (claims 28, 31, 34-44, 49 and 53) submitted in Applicants' Amendment filed November 17, 2007 have been withdrawn from consideration as allegedly being directed to a non-elected invention pursuant to 37 C.F.R. §1.142(b).

Pursuant to 37 C.F.R. §1.143, Applicants respectfully request reconsideration of the withdrawal of claims 28, 31, 34-44, 49 and 53 as presented in the Amendment filed November 17, 2007. Applicants respectfully request that claims 28, 31, 34-44, 49 and 53 be reinstated and fully considered along with the arguments submitted in the Amendment filed November 17, 2007 for the following reasons.

In response to the Restriction Requirement mailed, June 28, 2006, Applicants originally elected the invention of Group IV (originally filed claims 28-63) directed to a method of treating viral infection by administering a cholesterol sequestering agent to a mammal infected or suspected of being infected by an envelope virus. The newly submitted claims of the Amendment filed November 17, 2007, as shown in the listing of claims, are directed to a method of reducing viral load of a herpes infection by providing a beta-cyclodextrin. Newly submitted claim 28 recites as follows:

A method of reducing viral load of a herpes infection in an interstitial space of a mammal, the method comprising:

identifying a mammal suspected of having been infected by a herpes virus in an interstitial space;

providing said mammal an amount of a pharmaceutical composition consisting essentially of beta-cyclodextrin; and

measuring the reduction of the viral load of herpes in the interstitial space of the mammal.

The Office Communication alleges that claims 28, 31, 34-44, 49 and 53 are directed to an invention that is allegedly independent or distinct from the invention originally claimed. Specifically, the Office Communication alleges that while the inventions are directed to related processes, the inventions as claimed have 1) differing modes of operation and effect; and 2) do not encompass overlapping subject matter.

Pursuant to MPEP §806.05(j) related process inventions are distinct if:

- (1) the inventions *as claimed* do not overlap in scope, i.e., are mutually exclusive;
- (2) the inventions *as claimed* are not obvious variants; and
- (3) the inventions *as claimed* are either not capable of use together or can have a materially different design, mode of operation, function, or effect. Additionally, the burden is on the Examiner to provide an example to support the determination that the inventions are distinct.

Applicants respectfully submit that the invention of the newly submitted claims is not distinct from the invention originally elected. The inventions as claimed clearly overlap in scope and are not mutually exclusive. It is well known in the art that viral load is a measure of the severity of viral infection and that successful treatment of viral infection is typically performed by administering an agent that reduces viral load. For example, see Exhibit A (Clercq, *Clinical Microbiology Reviews*, 16:569-596, (Oct. 2003)) submitted herewith showing treatment of viral infection, specifically herpes virus, by administering agents that reduce viral load to reduce the severity of infection. Applicants submit that the inventions clearly overlap in scope because both inventions are directed to a method of treating a viral infection (*e.g.*, reducing viral load) in a mammal by selecting (*e.g.*, identifying) a mammal suspected of having been infected by an envelope virus (*e.g.*, herpes virus) and administering (*e.g.*, providing) a cholesterol sequestering agent (*e.g.*, beta-cyclodextrin) to the mammal. Regardless of the limitation of measuring the reduction in viral load recited in the newly submitted claims, the inventions clearly overlap and therefore are not distinct under MPEP §806.05(j).

Furthermore, the inventions are not distinct because they are capable of use together and do not have a materially different design, mode of operation, function, or effect. Both inventions are clearly capable of use together because the invention of the newly submitted claims is merely more narrowly drawn than the invention of the originally elected claims and simply requires an

additional step of measuring the reduction in viral load. The invention of the newly submitted claims does not exclude any limitation of the invention of the originally elected claims and therefore both inventions are clearly capable of use together. Additionally, both inventions as claimed have similar modes of operation and effect in contrast to the allegations presented in the Office Communication. For example, the mode of operation for both inventions is to provide for the treatment of viral infection (e.g., reduction of viral load) by administering (e.g., providing) a cholesterol sequestering agent (e.g., beta-cyclodextrin) to a mammal as described above. Similarly, the effect of both inventions is the treatment of viral infection by reduction of viral load in a mammal by administering a cholesterol sequestering agent (e.g., beta-cyclodextrin).

Additionally, Applicants respectfully submit that the Office Action fails to provide an example to support the determination that the inventions are distinct as required under MPEP §806.05(j). The Office Action alleges that the inventions are distinct because they have 1) differing modes of operation and effect; and 2) do not encompass overlapping subject matter. However, no example is presented providing support for such determination of distinctness as required.

For the aforementioned reasons, Applicants respectfully submit that the newly submitted claims are not directed to an invention that is independent or distinct from the invention originally claimed. Accordingly, Applicants respectfully request that claims 28, 31, 34-44, 49 and 53 be reinstated and fully considered along with the arguments submitted in the Amendment filed November 17, 2007.

In re Application of:
Scheele and Hildreth
Application No.: 10/625,090
Filed: July 22, 2003
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Atty Docket No.: JHU1710-4

Conclusion

In view of the above remarks, reconsideration of the withdrawal of claims 28, 31, 34-44, 49 and 53 as presented in the Amendment filed November 17, 2007 is respectfully requested. In light of such remarks, Applicants respectfully request that claims 28, 31, 34-44, 49 and 53 be reinstated and fully considered along with the arguments submitted in the Amendment filed November 17, 2007. The Examiner is invited to contact Applicants' undersigned representative if there are any questions relating to this application.

The Commissioner is hereby authorized to charge \$230.00 as payment for the One-Month Extension of Time fee (\$230.00), for small entity, to Deposit Account No. 07-1896. Additionally, the Commissioner is hereby authorized to charge any other fees that may be due in connection with the filing of this paper, or credit any overpayment to Deposit Account No. 07-1896 referencing the above-identified docket number.

Respectfully submitted,



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